

Application Number: 10/602,456
Balschmidt et al.
Filed: June 23, 2003
Attorney Docket No.: 6460.200-US
Via Facsimile No.: 571-273-8300

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REMARKS

The examiner states in the Office Action Summary that claims numbered 1, 3-11 and 13-23 are pending in the application, and claims numbered 1, 3-11 and 13-23 are rejected.

Claims numbered 1, 3-11 and 13-23 are amended herein. Following entry of this amendment, claims numbered 1, 3-11, and 13-23 are pending in the present application.

Claim Objections

(1) The examiner has objected to claims numbered 1, 3-11 and 13-23 because in claim 1, line 6 after "derivative of the analog of the peptide" should be changed to "a derivative of the analog of the peptide thereof."

Applicant has amended the language of claim 1 to incorporate the examiner's suggested corrections.

Applicant respectfully requests reconsideration and withdrawal of the objection to claims numbered 1, 3-11 and 13-23.

Claim Rejections – 35 U.S.C. § 103

(2) The examiner has rejected claims numbered 1, 3-11 and 13-23 under 35 U.S.C. § 103 (a) as being unpatentable over Marini, J.L. (U.S. 6,328,987) when taken with Herschler, R.J. (U.S. 4,973,605), and in view of Mudaliar et al. (Diabetes Care (1999) 22, 1501-1506), and in further view of DuBois (U.S. 6,576,653) and Drucker (U.S. 5,990,077). The examiner states Marini teaches, in the patent claims 1-3, a composition comprising human alpha interferon-2 and methylsulfonylmethane (dimethyl sulfone), and that the composition is an aqueous solution or suspension, and teaches topically administering the composition, but Marini does not teach the concentration of dimethyl sulfone administered. Herschler teaches that the suitable MSM concentration is about 5.5-10.9 mg/mL or about 61-121mM. DuBois teaches a GLP-1 analog is an insulinotropin, and is formulated in a pharmaceutical composition for treating diabetes. Drucker teaches a pharmaceutical composition comprising a GLP-2 for treating diabetes.

Applicant has amended claim number 1 to include functional language relevant to the

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isotonicity agent to clarify the role of the dimethyl sulfone with respect to the overall pharmaceutical composition. Support for this amendment is located on page 1, lines 13-15, of the specification as filed. Applicant respectfully requests the examiner afford patentable weight to the functional language in accordance with *In re Land*, 368 F.2d 866 (151 USPQ 621), *In re Swinehart*, 439 F.2d 210 (169 USPQ 226) and *In re Mills*, 916 F.2d 680 (16 USPQ 2d 1430).

Applicant respectfully requests reconsideration and withdrawal of the rejection of claims numbered 1, 3-11 and 13-23 under 35 U.S.C. § 103 (a).

(3) The examiner has rejected claims numbered 1, 3-11 and 13-23 under 35 U.S.C. § 103 (a) as being unpatentable over Pierce, s.w. (U.S. 6924273) when taken with Herschler, R.J. (U.S. 4,973,605), and in view of Mudaliar et al. (Diabetes Care (1999) 22, 1501-1506, and in further view of DuBois (U.S. 6,576,653) and Drucker (U.S. 5,990,077). The examiner states Pierce teaches, in claim 10, a composition comprising insulin and MSM, and at column 12, lines 12-14, a composition is aqueous solution or suspension, and in claim 5, the composition is suitable for various modes of administration. Pierce does not expressly teach the concentration of MSM administered. Herschler teaches that the suitable MSM concentration is about 5.5-10.9 mg/mL or about 61-121mM. DuBois teaches a GLP-1 analog is an insulinotropin, and is formulated in a pharmaceutical composition for treating diabetes. Drucker teaches a pharmaceutical composition comprising a GLP-2 for treating diabetes.

Applicant has amended claim number 1 to include functional language relevant to the isotonicity agent to clarify the role of the dimethyl sulfone with respect to the overall pharmaceutical composition. Support for this amendment is located on page 1, lines 13-15, of the specification as filed. Applicant respectfully requests the examiner afford patentable weight to the functional language in accordance with *In re Land*, 368 F.2d 866 (151 USPQ 621), *In re Swinehart*, 439 F.2d 210 (169 USPQ 226) and *In re Mills*, 916 F.2d 680 (16 USPQ 2d 1430).

Applicant respectfully requests reconsideration and withdrawal of the rejection of claims

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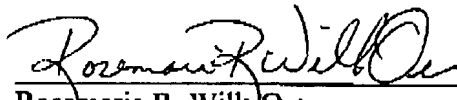
numbered 1, 3-11 and 13-23 under 35 U.S.C. § 103 (a).

- (4) Applicant has amended claims numbered 6-11 to clarify the subject matter of the claims.
Applicant has amended claims numbered 3-11 and 13-23 to correct antecedent basis.

The examiner is hereby invited to contact the undersigned by telephone if there are any questions concerning this response or application.

Respectfully submitted,

Date: September 24, 2007



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